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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,534	03/28/2002	Ubaldo Armato	17642-59	5010

33717 7590 07/26/2005

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,534

Applicant(s)

ARMATO ET AL

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A response of 5/10/05 to a restriction requirement of 4/20/05 elected with traverse invention I claims 13, 14 and 16-25.

The traverse is on the ground that a search for invention I will necessarily encompass a search for invention II. However, due to differences in conditions required by the different methods of inventions I and II, invention I can be searched without searching for invention II, or the converse. The traverse is unpersuasive, and the restriction requirement is adhered to and made final.

Claims 15 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/10/05.

Claims examined on the merits are 13, 14 and 16-25.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 16-21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1651

Support for these claims in the specification is not readily apparent. Applicants have pointed to pages for support. However, support is not found on the pages cited. Pages 16 and 17 are indicated as supporting claims 16-18. However, these pages list publications as bibliographic sources. Page 18, lines 21-23, does not disclose claim 19, and page 19, lines 14-26, does not disclose claim 20. Claim 21 is not found at page 21, lines 7-9. Page 15 like pages 16 and 17 lists bibliographic sources, and does not disclose claims 23 and 24.

10 ***Claim Rejections - 35 USC § 112***

Claims 13, 14 and 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Bridging lines 1 and 2 of claim 13, "bio-membrane using---- fibroin" is unclear as to how the membrane uses the fibroin. It appears "using" should be replaced with --- including ---.

The term bio-membrane, in line 1 of claim 13 is uncertain as to meaning and scope. How does "bio" define the membrane? Additionally, structure that is a membrane and not a membrane is unclear since no structure that defines a membrane is required.

20 In line 4 of claim 13, the meaning and scope of "specialized tissue cells" is uncertain. Whether a cell is "specialized" is relative and subjective.

In line 3 of claim 21, the meaning and scope of "normal cytological features" is uncertain. Being "normal" is relative and subjective.

Bridging lines 1 and 2 of claim 23, "includes comprises" is
5 uncertain as to meaning.

Claim Rejections - 35 USC § 103

Claims 13, 14 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santin et al or Gotoh et al (listed on form 1449) in view of Minoura et al and Naughton et al (4,963,489) (both
10 newly applied), and if necessary in further view of Bell (6,398,819) (newly applied).

The claims are drawn to forming tissue by seeding cells on a bio-membrane including crystalline beta-form fibroin, and proliferating and differentiating the cells to form tissue.

15 Santin et al and Gotoh et al disclose preparing a fibroin film in the same way as described in the present specification when preparing a fibroin membrane. The film adheres cells, and the fibroin film is formed on synthetic polymer plate or film. See Santin et al (page 383 under "Sample preparation"), and Gotoh et al (page 352, under
20 "Preparation of aqueous solutions of NSF and RSF" and "Preparation of SF matrices for cell culture experiments").

Minoura et al disclose attachment and growth of fibroblast cells on silk protein matrices. The proteins exhibited as high a cell attachment and growth as collagen widely used as a cell culture

Art Unit: 1651

substrate (sentence bridging the columns in the abstract on page 1215).

Naughton et al disclose growing cells to produce tissue on a collagen substrate (col 1, line 36, and col 38, lines 37-38).

5 Bell discloses producing tissue by culturing cells on an extracellular matrix scaffold formed of collagen. For example, see col 1, line 56 to col 2, line 14, and col 6, line 8.

It would have been obvious to use the fibroin film of Santin et al or Gotoh et al as a substrate for culturing cells to produce tissue as suggested by Minoura et al disclosing that silk protein matrices exhibit as high a cell attachment and growth as collagen and Naughton et al disclosing growing cells to produce tissue on a collagen substrate, and if needed, by Bell disclosing using an extracellular matrix formed of collagen for culturing cells to produce tissue. The
10 fibron of Santin et al or Gotoh et al is crystalline beta-form. Growing cells to produce tissue will inherently result in proliferation and differentiation. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. Using specific cells or cells from a specific
15 source would have been obvious to obtain tissue produced by the specific cells or cells from the source. Providing glucose to the cells as in claim 18 would have been obvious when the cells utilize glucose as a nutrient source. Pre-irradiated cells as in claim 21 encompasses exposing cells to light. Cells grown on the film of
20 Santin et al or Gotoh et al will inherently be exposed to light before
25

Art Unit: 1651

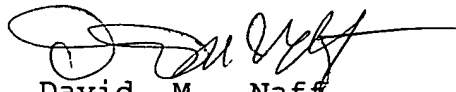
culturing. The film of Santin et al or Gotoh et al will contain an amount of fibroin as required by claim 25.

Conclusion

Any inquiry concerning this communication or earlier
5 communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
the examiner's supervisor, Mike Wityshyn can be reached on 571-272-
10 0926. The fax phone number for the organization where this
application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be
obtained from the Patent Application Information Retrieval (PAIR)
system. Status information for published applications may be obtained
15 from either Private PAIR or Public PAIR. Status information for
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direct.uspto.gov. Should you have questions on access to the Private
PAIR system, contact the Electronic Business Center (EBC) at 866-217-
20 9197 (toll-free).


David M. Naff
Primary Examiner
Art Unit 1651